

REMARKS

Rejections under 35 U.S.C. §112

1. The Examiner rejects claims 1-18 and 22-27 as not complying with the enablement requirement of 35 U.S.C. §112, first paragraph. In particular, the Examiner cites page 8, line 21 of the specification ("The target material must be coupled to the biofilm by a coupling medium.") as limiting the invention to those embodiments in which a coupling medium is used.

Although the Applicants do not concede the Examiner's assertion, this rejection is moot in light of the current amendments.

2. The Examiner rejects claims 1-4, 13-23, and 25-27 as not complying with the enablement requirement of 35 U.S.C. §112, first paragraph. In particular, the Examiner cites page 8 of the specification as requiring the use of a target material.

Although the Applicants do not concede the Examiner's assertion, this rejection is moot in light of the current amendments.

3. The Examiner rejects claims 1-27 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner asserts that the phrase "capsular" as used, e.g., on page 5, line 7 of the specification has not been defined, and is therefore vague.

The Applicants have previously indicated that this term is well-known in the biological arts. Although the Examiner apparently does not disagree, the Examiner maintains this rejection and invites the Applicants to precisely define the term.

The Applicants do not believe 35 U.S.C. §112 imposes such a burden. To comport with the requirements of 35 U.S.C. §112, the Applicants merely must provide "a written description of the invention, and of the manner and process of making and using it, in such full, clear,

concise, and exact terms as to enable *any person skilled in the art to which it pertains*, or with which it is most nearly connected, to make and use the same...."

Nevertheless, in the interest of advancing prosecution, the Applicants note that some bacteria sometimes produce a capsule-shaped layer of polysaccharides. In the context of these bacteria, the term "capsular" indicates a pertinence to this capsule. Polysaccharides which can be found within such a capsule are examples of "capsular polysaccharides."

4. The Examiner rejects claims 15, 19, and 22 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention.

As for claim 15, the Applicants note that the phrase "capsular polysaccharide" has a well-known meaning in the biological arts.

As for claim 19, the Applicants do not concede that the previously-pending claim was vague or indefinite. Nevertheless, claim 19 is amended.

As for claim 22, although the Applicants do not concede that the phrase "associated" was vague or indefinite, this claim is amended.

Rejections under 35 U.S.C. §102

5. The Examiner rejects claims 1, 13-16, and 22-27 under 35 U.S.C. §102(b) separately under 37 Journal of Antimicrobial Chemotherapy, pp. 377-381 ("Wilson") and J. Periodont. Res., 28, pp. 204-210 ("Sarkar").

Independent claim 1 is amended to recite contacting the biofilm, compound, or coupling medium with a target. *Sarkar* does not show or suggest contacting a biofilm, compound, or coupling medium with a target. For at least this reason, the Applicants believe that claim 1 is patentable.

Independent claim 25 is amended to recite causing a target coupled to the biofilm by a coupling medium to expose the biofilm to stress waves. *Sarkar* does not show the use of a

target, much less causing a target to expose a biofilm to stress waves. For at least this reason, the Applicants believe that claim 25 is patentable.

Independent claim 26 is amended to recite exposing a target coupled to the biofilm via a coupling medium to one or more stress waves. *Sarkar* does not show the use of a target, much less exposing a target coupled to a biofilm to one or more stress waves. For at least this reason, Applicants believe that claim 26 is patentable.

6. The Examiner rejects claims 1, 13-16, and 22-27 under 35 U.S.C. §102(b) under 37 Journal of Antimicrobial Chemotherapy, pp. 377-381 ("*Wilson*"). Independent claim 1 is amended to recite contacting the biofilm, compound, or coupling medium with a target. *Wilson* does not show or suggest contacting a biofilm, compound, or coupling medium with a target. For at least this reason, the Applicants believe that claim 1 is patentable.

Independent claim 25 is amended to recite causing a target coupled to the biofilm by a coupling medium to expose the biofilm to stress waves. *Wilson* does not show the use of a target, much less causing a target to expose a biofilm to stress waves. For at least this reason, the Applicants believe that claim 25 is patentable.

Independent claim 26 is amended to recite exposing a target coupled to the biofilm via a coupling medium to one or more stress waves. *Wilson* does not show the use of a target, much less exposing a target coupled to a biofilm to one or more stress waves. For at least this reason, Applicants believe that claim 26 is patentable.

7. The Examiner rejects claims 1, 13-15, and 25-27 under 35 U.S.C. §102(b) under Colloids and Surfaces B: Biointerfaces, 9, pp. 239-245 ("*Qian*").

Independent claim 1 is amended to recite contacting the biofilm, compound, or coupling medium with a target. *Qian* does not show or suggest contacting a biofilm, compound, or coupling medium with a target. For at least this reason, the Applicants believe that claim 1 is patentable.

Independent claim 25 is amended to recite causing a target coupled to the biofilm by a coupling medium to expose the biofilm to stress waves. *Qian* does not show the use of a target, much less causing a target to expose a biofilm to stress waves. For at least this reason, the Applicants believe that claim 25 is patentable.

Independent claim 26 is amended to recite exposing a target coupled to the biofilm via a coupling medium to one or more stress waves. *Qian* does not show the use of a target, much less exposing a target coupled to a biofilm to one or more stress waves. For at least this reason, Applicants believe that claim 26 is patentable.

8. The Examiner rejects independent claim 25 under 35 U.S.C. §102(b) under Letters in Applied Microbiology, 24, pp. 177-179 ("Sadoudi"). Claim 25 is amended to recite "causing a target coupled to the biofilm by a coupling medium to expose the biofilm to" stress waves. *Sadoudi* does not show the use of a target, much less causing a target to expose a biofilm to stress waves. For at least this reason, the Applicants believe that claim 25 is patentable.

Rejections under 35 U.S.C. §103

9. The Examiner rejects dependent claims 5-12 and 19-21 as being unpatentable over *Sarkar* in view of WO 09/23325 ("Kollias"). Currently amended independent claim 1 recites a feature previously recited in dependent claim 5. The Examiner concedes that *Sarkar* fails to teach "the apparatus of claims 5-12 and 19-21,"¹ but asserts that *Kollias* teaches the "using laser-induced impulse transients to deliver compounds, such as therapeutic agents, to epithelial cells."

To establish a *prima facie* case of obviousness, there must be a reasonable expectation of success of combining the teachings of two references.² The Applicants submit that there is no reasonable expectation of success in the Examiner's proposed combination. In particular, the biofilm samples in *Sarkar* were obtained by scraping a patient's tooth with a swab, thereby

¹ *Office Action of November 8, 2006*, p. 8. The Applicants note that claims 5-12 and 19-21 are each directed to a method, not an apparatus.

² MPEP §706.02(j).

obtaining a small amount of biofilm. Then, the biofilm was deposited in a solution, to which toluidine blue O was added. Finally, the biofilm/solution mixture was irradiated with a laser while it was being mixed.³

At any point after the biofilm was scraped from the patient's tooth, there is no reasonable way to couple a target to the biofilm. For example, once the biofilm is mixed with the solution, it would be impossible to keep the biofilm fixed for a long enough time to attach the target. Furthermore, even if it were possible to couple a target to the biofilm prior to irradiation, the target would be separated from the biofilm by the force of the mixing. Hence, there is no reasonable expectation that any of the effects described in *Kollias*, which are predicated on the effective coupling of the target to the epithelial cells, would result in the case of the process described in *Sarkar*.

For at least these reasons, the Applicants submit that claim 1 is patentable.

10. The Examiner rejects dependent claims 5-12 and 19-21 as unpatentable over *Wilson* in view of *Kollias*. Currently amended independent claim 1 recites a feature previously recited in dependent claim 5. The Examiner concedes that *Wilson* fails to teach "the apparatus of claims 5-12 and 19-21,"⁴ but asserts that *Kollias* teaches the "using laser-induced impulse transients to deliver compounds, such as therapeutic agents, to epithelial cells."

The Applicants submit that there is no reasonable expectation of success in modifying *Wilson* in view of *Kollias*. *Wilson* generally describes techniques of "[p]hotodynamic therapy (PDT), which involves the use of light-activated drugs."⁵ The experiment described in *Wilson* involved irradiating a biofilm on which a photosensitiser (AlPcS₂) was applied.⁶ According to *Wilson*, the photosensitiser, "on irradiation with light of suitable wavelength, generates singlet oxygen and free radicals which can kill the organism[s]" that make up the biofilm.⁷

³ *Sarkar*, p. 205.

⁴ *Office Action*, p. 9.

⁵ *Wilson*, p. 377.

⁶ *Id.*, at 378.

⁷ *Id.*, at 377.

However, when a target material is disposed over the biofilm, the laser irradiates the target material and *not* the photosensitisers on the biofilm. Such a configuration would eviscerate the role of the photosensitiser. Indeed, "in the absence of AlPcS₂, exposure of the 4-day old biofilms of *S. sanguis* to 12.2 J of light from the GaAlAs laser did not lead to any significant decrease in the viability count [of bacteria that comprise the biofilm]."⁸ Thus, there is no reasonable expectation that the results described in *Wilson* would persist if the target – and not the photosensitisers – were irradiated. For at least this reason, the Applicants submit that claim 1 is patentable.

Conclusion

All the dependent claims are patentable for at least the reason that they depend on a patentable independent claim. Cancelled claims have been cancelled without prejudice or disclaimer.

A Petition for Extension of Time with the appropriate fee is being submitted herewith via EFS. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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⁸ *Wilson*, p. 379.